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10/588,696	08/08/2006	Friedbert Wechs	2037.8	9927

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EXAMINER	
CHRISTIAN, MARJORIE ELLEN	
ART UNIT	PAPER NUMBER
4112	
MAIL DATE	DELIVERY MODE
07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,696	WECHS ET AL.	
	Examiner	Art Unit	
	MARJORIE CHRISTIAN	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office action based on the application filed August 8th, 2006.

2. Claims 1-20 are pending and have been fully considered.

3. The preliminary amendment filed August 8th, 2006 has been entered.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Information Disclosure Statement

6. The information disclosure statement filed 8/8/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. There is no copy of foreign patent document EP 828553. It has been placed in the application file, but the information referred to therein has not been considered.

7. The information disclosure statement filed 8/8/2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. There is no concise explanation of relevance for foreign patent documents: EP 828553, EP 0168783 and JP 04094727. It has been placed in the application file, but the information referred to therein has not been considered.

8. The other items in the information disclosure statement have been considered, items not considered have been lined through.

Specification

9. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

10. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. The term "essentially" in claim 8 is a relative term which renders the claim indefinite. The term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

13. Claims 1-11 are rejected because the limitation "the lumen" is recited in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

14. Claims 1, 3-10, 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-20 of copending Application No. 10/588,695. Although the conflicting claims are not identical, they are not patentably distinct from each other. The instant claims 1 and 12 have an ultrafiltration rate in albumin solution in the range of 5 to 25 ml/(h.m^2.mmHg), whereas the copending claims 1 and 12 have an ultrafiltration rate in the range of 25 to 60 ml/(h.m^2.mmHg), which overlaps with the present range. The sieving coefficient of cytochrome c in the instant claims 1 and 12 is expressed by a relation, whereas the copending claims discloses the sieving coefficient of cytochrome c as a minimum of 0.8. Using the ultrafiltration rate range disclosed by the copending claims 1 and 12, the relation disclosed by the instant claims 1 and 12 was satisfied in that it is higher 0.8. As further evidence that the copending and instant claims overlap in scope, and therefore

are not patentably distinguishable, the instant specification discloses that the minimum sieving coefficient for cytochrome c is preferably 0.8 (Page 11, Lines 1-2). Therefore the sieving coefficient disclosed by the copending application claims 1 and 12 are within range of the relation disclosed in the instant claims 1 and 12. Instant claims 3-10, 13-20 are identical to copending claims 2-10 and 13-20.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by SLUMA et al. US Patent No. 5,290,448 (hereinafter SLUMA).

17. As to Claim 1, SLUMA discloses a semi-permeable membrane in the form of a hollow fiber (Abstract) comprising: a synthetic first polymer possessing an open-pored integrally asymmetric structure across its wall (Figures 2-5); the skin has a thickness of 0.1 to 0.2 microns on the inside of the cavity (SLUMA, Claim 3) ***[porous separating layer of thickness between 0.1 and 2 μm on the inner surface facing the lumen]***; an

ultrafiltration rate in albumin solution of 13 mL/(m².h.mmHg) (Example 3) ***[ultrafiltration rate in albumin solution in the range 5 to 25 ml/(m².h.mmHg)]***; the albumin screen coefficient is 0 (Example 3) ***[hollow fiber membrane has a maximum sieving coefficient for albumin of 0.005]***, where no additives are present and properties were measured after drying (Example 1, Column 4, Lines 13-14) ***[in absence of additives stabilizing the pores in the membrane wall and after prior drying]*** and the screen coefficient in Example 3 satisfies the relation shown below ***[sieving coefficient for cytochrome c that satisfies the relation].***

$$SCcc \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}{}^{3} - 0.004 \cdot UFR_{Alb}{}^{2} + 0.1081 \cdot UFR_{Alb} - 0.25$$

$$0.61(SCcc) \geq 0.59$$

18. As to Claim 9, SLUMA discloses a screen coefficient for albumin of 0 (Example 3) ***[maximum sieving coefficient for albumin of 0.003].***

19. As to Claim 11, SLUMA discloses an ultrafiltration rate of albumin of 13 ml/(m².h.mmHg) (Example 3) ***[ultrafiltration rate in albumin solution in the range of 10 to 25 ml(m².h.mmHg)].***

20. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by SLUMA et al. US Patent No. 5,290,448, as evidenced by DUNWEG et al. US Patent No. 5,505,859 (hereinafter DUNWEG).

21. As to Claim 2, SLUMA discloses a semi-permeable membrane in the form of a hollow fiber as shown in the 102(b) rejection of Claim 1. The structure recited by SLUMA is not lacking and therefore the function disclosed by Claim 2 is inherent (see MPEP 2112.01) as further evidenced by DUNWEG. DUNWEG discloses a porous hollow fiber membrane where the ultrafiltration rate of water is 59 mL/(m^2.h.mmHg), filtration coefficient of cytochrome c is 0.88 and filtration coefficient of albumin is 0.08, where the anticipated ultrafiltration rate of albumin is a factor of ten below that of water (DUNWEG Example 3).

$$SCcc \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}{}^{3} - 0.004 \cdot UFR_{Alb}{}^{2} + 0.1081 \cdot UFR_{Alb} - 0.12$$

$$0.88(SCcc) \geq 0.389$$

Therefore, absent any evidence to the contrary, it is the Examiner's position that the sieving coefficient for cytochrome c of SLUMA is conventional and consistent with DUNWEG.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. Claims 3-8 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,290,448 SLUMA et al. (hereinafter SLUMA) in view of US Patent No. 4,906,375, HEILLMAN (hereinafter HEILMANN).

24. As to Claims 3 and 4, SLUMA discloses the semi-permeable membrane in the form of a hollow as shown above in the 102(b) rejection of Claim 1. SLUMA does not appear to expressly disclose the use of hydrophobic and hydrophilic polymers. However, HEILMANN discloses that the microporous hollow fiber is made up of a first hydrophobic polymer and second hydrophilic polymer (Abstract) ***[synthetic first polymer is a hydrophobic polymer and the hollow fiber membrane also has a second hydrophilic polymer]***.

* SLUMA and HEILMANN are analogous art because they are from the same field of endeavor, microporous hollow fibers for blood purification.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hollow fiber of SLUMA to include the hydrophilic and hydrophobic polymers of HEILMANN. The motivation would have been to have a hollow fiber with very good hydraulic permeability and excellent mechanical strength (HEILMANN, Column 3, Lines 55-57). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

25. As to Claims 5 and 6, HEILMANN discloses that the hydrophobic first polymer consists of polysulfone such as polyethersulfone and more specifically polymeric aromatic polysulfone (Column 4, Lines 44-46).

26. As to Claim 7, HEILMANN discloses that the hydrophilic second polymer may be polyvinylpyrrolidone (Column 5, Lines 17-18).

27. As to Claim 8, HEILMANN discloses that next to microporous barrier layer on the outside is a foam-like supporting structure that is different to the lamellae-like structures of the prior art (Column 9, Lines 51-54) ***[supporting layer extends from the separating layer across essentially the entire wall of the hollow-fiber membrane and has a sponge-like structure that is free from finger pores].***

28. Claim 10 is rejected under 35 USC 103 (a) as being obvious over US Patent No. 5,290,448 SLUMA et al. (hereinafter SLUMA) in view of US Patent No. 5,476,715 OTTO (hereinafter OTTO).

29. As to Claim 10, SLUMA discloses the semi-permeable membrane in form of a hollow as shown above in the 102(b) rejection of Claim 1 . SLUMA does not appear to explicitly disclose the polyelectrolyte in the separating layer. However, OTTO discloses an adsorbent material comprising homo- or co- polymers of acrylic acid that are bound to the carrier material (Column 4, Lines 39-44) ***[polyelectrolyte with negative fixed charges is bound in the separating layers].***

* OTTO and SLUMA are analogous art because they are from the same field of endeavor, blood purification with porous materials.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the semi-permeable hollow fiber of SLUMA to include the polyelectrolyte in the separating layer of OTTO. The motivation would have been to eliminate biomacromolecules from a whole blood circuit (OTTO, Abstract). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

30. Claims 12-20 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 4,906,375, HEILLMANN (hereinafter HEILMANN) in view of US Patent No. 5,476,715 OTTO (hereinafter OTTO) as further evidenced by US Patent No. 5,290,448 SLUMA et al. (hereinafter SLUMA).

31. As to Claim 12, HEILMANN discloses a method of producing microporous hollow fibers (Claim 1) ***[method for producing a semipermeable hollow-fiber membrane]*** comprising: a polymer solution with 12 to 20% by weight of the first polymer (Claim 1(a)) ***[preparing a homogenous spinning solution comprising 12 to 30 wt. % of a synthetic first polymer]***; passing the spinning solution through an external ring and an internal hollow core to create an asymmetric microporous wettable hollow fiber (HEILMANN, Claim 1) ***[extruding the spinning solution through the annular slit of a hollow-fiber die to give a hollow fiber]***; simultaneously passing the precipitant solution

through the hollow internal core (HEILMANN, Claim 1) ***[extruding an interior filler through the central opening of the hollow fiber die]***; passing a precipitant solution through the internal core comprising a solvent and nonsolvent (HEILMANN, Claim 1) ***[interior being a coagulation medium for the synthetic first polymer comprising a solvent and non-solvent for the synthetic polymer]***; passing a precipitant solution through the internal core, where it naturally flows that the solution is passed to initiate coagulation of the interior (HEILMANN, Claim 1) ***[bringing the interior filler into contact with the inner surface of the hollow fiber to initiate coagulation in the interior]***; that the fiber manufactured has an inner microporous barrier and outer supporting structure (Column 9, Lines 49-54) ***[formation of a separating layer on the inner surface and formation of a membrane structure]***; the coagulated fiber is rinsed in a bath for fixing the microporous structure (Column 9, Lines 35-40) ***[passing the hollow fiber through a coagulation bath to complete formation of the membrane structure and to fix the membrane structure]***; dissolving out and washing away a substantial portion of the polyvinyl pyrrolidone and solvent to form a fiber (HEILMANN, Claim 1) ***[extracting the hollow fiber membrane to remove the solvent system and soluble substances]***; and the fiber is passed through a hot drying zone (Column 9, Lines 41-42) ***[drying the hollow fiber membrane].***

HEILMANN does not appear to explicitly disclose that the interior filler contains a polyelectrolyte. However, OTTO discloses the use of polycarboxylic acid ***[a***

polyelectrolyte with negative fixed charges] in the carrier material ***[in the interior filler]*** (Column 3, Lines 36-40).

HEILMANN further discloses the hollow fiber of Claim 1 including a hollow fiber for hemodialysis (Abstract) comprising: a synthetic first polymer possessing an open-pored integrally asymmetric structure across its wall (HEILMANN, Figure 1B); the hollow fiber has a microporous barrier layer with a pore diameter of 0.1-2 microns (HEILMANN, Claim 9) ***[porous separating layer of thickness between 0.1 and 2 μm on the inner surface facing the lumen]***; next to the barrier layer on the outside is a foam-like supporting structure (Column 9, Lines 51-54) ***[an open-pored supporting layer adjoining the separating layer].*** The structure recited by HEILMANN is not lacking and therefore the functional characteristics recited are inherent (see MPEP 2112.01) as further evidenced by SLUMA. SLUMA discloses an ultrafiltration rate in albumin solution of 13mL/(m².h.mmHg) (SLUMA, Example 3) ***[ultrafiltration rate in albumin solution in the range 5 to 25 ml/(m².h.mmHg)]***; the albumin screen coefficient is 0 (SLUMA, Example 3) ***[hollow fiber membrane has a maximum sieving coefficient for albumin of 0.005]***, where no additives are present and properties were measured after drying (see Example 1, Column 4, Lines 13-14) ***[in absence of additives stabilizing the pores in the membrane wall and after prior drying]***, where the screen coefficient in Example 3 satisfies the relation shown below ***[sieving coefficient for cytochrome c that satisfies the relation].***

$$SCcc \geq 5 \cdot 10^{-5} \cdot UFR_{Alb}^{\ 3} - 0.004 \cdot UFR_{Alb}^{\ 2} + 0.1081 \cdot UFR_{Alb} - 0.25$$

$$0.61(SCcc) \geq 0.59$$

* HEILLMANN and OTTO are analogous art because they are from the same field of endeavor, blood purification with porous materials.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of producing a microporous hollow fiber of HEILLMANN to include the polyelectrolyte in the interior filler of OTTO. The motivation would have been to eliminate biomacromolecules from a whole blood circuit (OTTO, Abstract). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

32. As to Claims 13 and 14, HEILMANN (in view of OTTO) discloses that the wet spinning solution contains 12 to 20% by weight of the hydrophobic first polymer (Column 13, Lines 1-3) ***[synthetic first polymer is a hydrophobic first polymer]*** 2 to 10% by weight of the polyvinylpyrrolidone (PVP) (Column 13, Lines 1-4) ***[spinning solution comprises 0.1 to 30wt.% of a hydrophilic second polymer]***, where PVP is the second hydrophilic polymer (Column 5, Lines 17-18).

33. As to Claim 15, HEILMANN (in view of OTTO) discloses that the hydrophobic first polymer consists of polysulfone such as polyethersulfone and more specifically polymeric aromatic polysulfone (Column 4, Lines 44-46).

34. As to Claim 16, HEILMANN (in view of OTTO) discloses that the hydrophilic second polymer may be polyvinylpyrrolidone (Column 5, Lines 17-18).

35. As to Claim 17, HEILMANN (in view of OTTO) discloses the use of a polar aprotic solvent in the solution (Column 5, Line 60 and Claim 1(b)) ***[solvent system comprises a polar aprotic solvent].***

36. As to Claims 18 and 19, OTTO discloses the use of the polycarboxylic acid, specifically homo or co- polymers of acrylic acid in the carrier material (Column 3, Lines 36-40) ***[polyelectrolyte is polycarboxylic acids that are homo- or copolymers of acrylic acids].***

37. As to Claim 20, OTTO discloses that 200mg of polyacrylic acid is used in approximately 50g of carrier material (Example 1) ***[proportion by weight of the polyelectrolyte is 0.01 to 1wt. % relative to the weight of the interior filler].***

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: foreign patent document JP 04/94727 as it discloses dipping a semipermeable membrane in polyacrylic acid.

39. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Patent Training Academy, Monday through Thursday 8-5pm (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on (571)272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

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